(12) UK Patent Application (19) GB (11) 2 227 176 (13) A

(43) Date of A publication 25.07.1990

(21) Application No 8928009.3

(22) Date of filing 12.12.1989

(30) Priority data
(31) 282671 (32) 12.12.1988 (33) US

(51) INT CL⁵
A61L 27/00 25/00

(52) UK CL (Edition K)
A5R RAG

(56) Documents cited
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(58) Field of search
UK CL (Edition J) A5R RAG RD1
INT CL⁴ A61L 15/06 17/00 25/00 27/00 31/00

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(54) Textured micro implants

(57) An improved micro-implantation method and apparatus for filling depressed scars, unsymmetrical orbital floors, and superficial bone defects is provided for use in reconstructive surgery procedures. The method employs textured micro particles having an outside diameter between about 20 and 3000 microns which may be injected with an appropriate physiologic vehicle and hypodermic needle and the syringe into a predetermined locus, such as, for example, into the base of depressed scars, beneath the skin in areas of depression and beneath the perichondrium or periosteum in surface irregularities of bone and cartilage. These textured micro particles have been found to enable the filling of defects in reconstructive surgery and because of their textured surface tissue ingrowth is encouraged, so that dislodgement and migration is prevented.

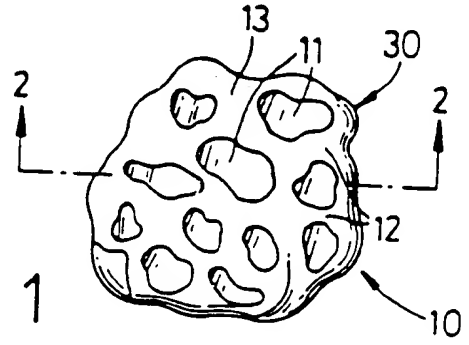

Fig. 1

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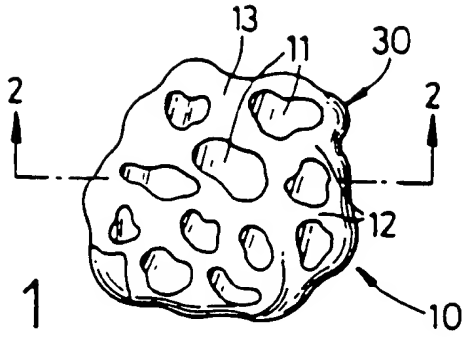

Fig. 1

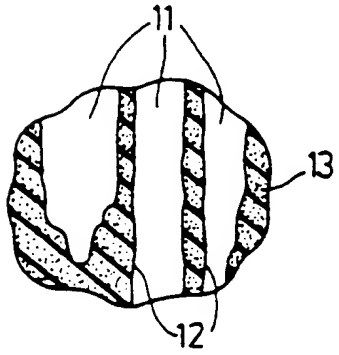

Fig. 2

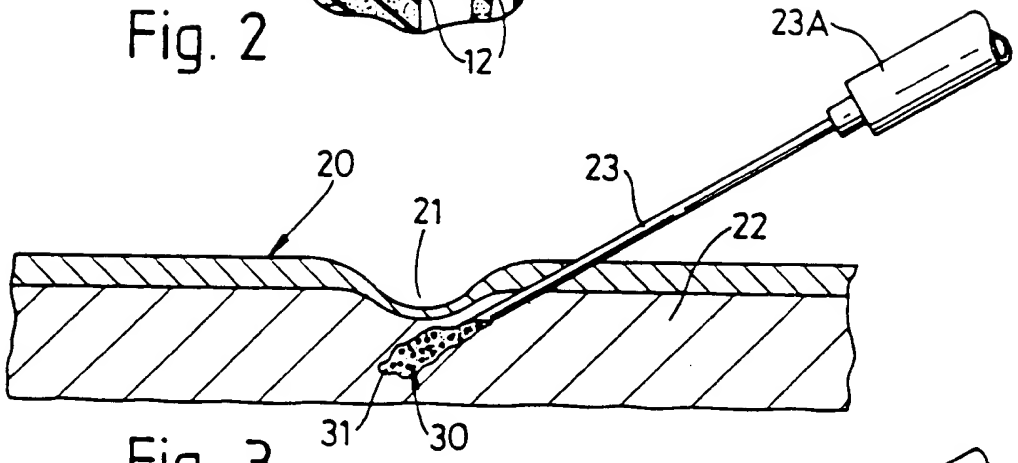

Fig. 3

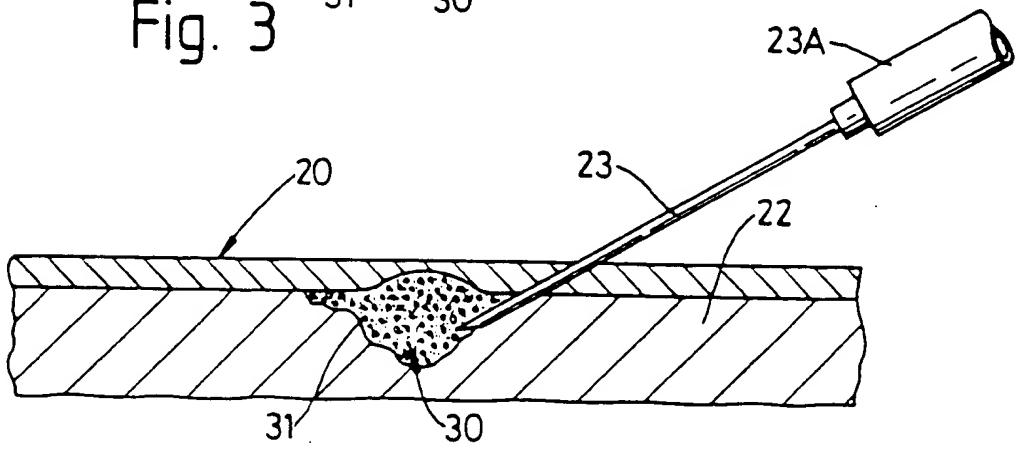

Fig. 4

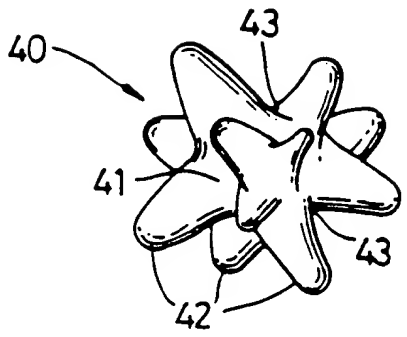

Fig. 5

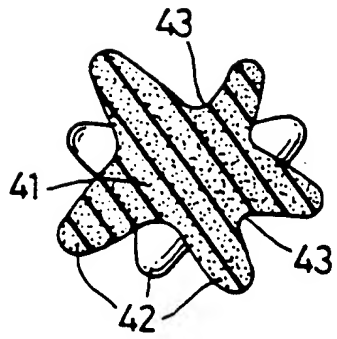

Fig. 6

TEXTURED MICRO IMPLANTS

BACKGROUND OF THE INVENTION

The present invention relates generally to the field of surgery and more particularly to surgery directed to the repair of injuries or defects, usually considered plastic and reconstructive surgery of the human body.

In the practice of plastic and reconstructive surgery, it is often necessary to employ the use of tissue or foreign materials to provide a means to fill in defects which may be present in the human body. One such defect which occurs is enophthalmus wherein one eyeball cannot be coordinated with the other due to differences in the volume of the orbital contents which may have been created by either trauma or developmental anomaly. Such a volume defect prevents coordination of binocular vision, interferes with appropriate opening and closing of defective eyelids, and adversely affects appearance. Traumatic or surgically altered bones, skin and subcutaneous tissue often have similar defects that interfere with form, function, or both. In the practice of plastic and reconstructive surgery, inert materials have frequently been implanted to fill these defects. Recently, various collagen compounds and fibrin matrices have been injected to fill these defects. Another prior art technique is to use adjacent or distant autologous tissues. Also, but on a rare or infrequent basis, cadaver and other species tissues have been used for fill-in substances. Liquid silicone has been used in the past as an injectable substance

for very small defects. Although some scar tissue forms around the silicone liquid droplets, it is subject to rampant and distant migration throughout the body and the ultimate location for such substances tends to be unpredictable. As a result, liquid silicone has generally been viewed as a dangerous substance by most plastic surgeons. Although it has been useful in controlled studies in very small (one-tenth of a cc. to 1 cc.) injections, it is currently not approved for general use because of its tendency to migrate.

In accordance with the present invention, textured micro particles are employed as a substance for use in reconstructive surgical procedures. Textured micro particles having an outside diameter of between about 20 and 3000 microns (or between approximately 0.002 and 3 cm.) may be injected into the body along with an appropriate physiologic vehicle to enable the filling of defects. A preferred range lies between about 20 and 3000 microns. Accordingly, and in accordance with the present invention, textured micro particles may be employed which are fabricated from an elastomer such as silicone, an inert material such as polytetrafluoroethylene (Teflon), ceramics or other inert substance. These textured micro particles may be introduced and placed at a precise location, and because of the textured configuration, tissue ingrowth will prevent dislodgement and ultimate migration. Furthermore, any over-correction can be readily adjusted by use of blunt cannulas and suction which provides for safe removal.

SUMMARY OF THE INVENTION

In accordance with the present invention, textured micro particles having a nominal diameter of between about 20 and 3000 microns (.002 to 3.0 mm) are selected. These textured micro particles present generally amorphous surfaces, and normally possess indentations ranging in size from, for example, 10 to 500 microns, with the indentations having irregular configurations and surfaces. Furthermore, a minimal inter-indentation distance is provided so that the particles may be injected through an appropriate hypodermic needle of the appropriate preselected size, and with or without an appropriate physiologic vehicle. Examples of appropriate physiologic vehicles are saline, various starches, polysaccharides, organic oils or fluids, all of which are well known and utilized in the art. Organically compatible vehicles are, of course, utilized. An organically compatible saccharide such as glucose has been found useful. Vehicles such as aqueous solutions of starch may also be employed. In certain instances, it may be desirable to employ a totally inert vehicle such as silicone oils or the like. Certain fats may also be found useful. In this connection, one highly compatible vehicle are esters of hylauranic acids such as ethyl hylauranodate and polyvinylpyrrolidone. Additionally, polyvinylpyrrolidone, hylauranodate, collagen and other biocompatible substances may be incorporated into the elastomer or combined with its surface.

It certain instances, it has been found desirable to utilize a surface modifier in combination with the micro particles, with materials such as polyvinylpyrrolidone, collagen, or hylauranodates having been found suitable. These surface modifiers assist in detoxification, and render the surface of the particles more susceptible to tissue ingrowth. In this connection, the surface modifiers such as polyvinylpyrrolidone may be mixed into the substance of or with the micro particles, and furthermore may thereafter be coated with a layer of a hylauranodate or hylauranic acid. Specifically a material such as hylauranic acid may be attached to the micro particle surface either through physical or chemical bonding.

Once implanted, the body will form a thin scar tissue around the implants so as to provide initial encapsulation. Polyvinylpyrrolidone, hylauranodate or collagen or other biocompatible substances may be chemically or physically combined with the particle substance or its surface to enhance the acceptance of the implant by the host. While in most situations the particles are of random size and configuration, but within the constraints of size indicated, it is generally desirable that the particles be of generally uniform configuration whenever possible.

For example, for soft tissue, a soft elastomer such as silicone rubber is a desirable material for the textured particles. When a firm area is being treated, such as connective

tissue or the like, polytetrafluoro-ethylene (Teflon™) or polyethylene may be satisfactorily utilized. In those instances wherein the requirement is for hard substances, biocompatible materials such as certain calcium salts including hydroxyapatite or other such crystalline materials, biocompatible ceramics, biocompatible metals such as certain stainless steel particles, or glass may be utilized.

By way of further background, the average diameter of a capillary is approximately 16 microns, or roughly two times the diameter of a red cell. Therefore, since the size of the textured micro particles is in the area of approximately 30 microns, they will not be absorbed into the capillaries, but will on the other hand, remain generally captive and fixed in place. Smaller particles, in the sub-micron range, have been implicated in causing inflammation and may be ingested by host cells. Thus, particles in the preferred range of between about 30 and 3000 microns are normally preferred.

The fibroblast cell is the scar-forming cell of the human body, and these cells range in size from between about 20 up to about 100 microns, and because of contact guidance, it will form a scar tissue or collagen-based coating around an inert foreign body. Furthermore, such scar tissue will conform to the irregularities in the surface of the foreign body, particularly if they are of sufficient size to accommodate tissue ingrowth. Our previous studies (American Society of Artificial Internal

Organs; U.S. Patent Nos. 3,638,649; 3,657,744; 4,239,492; and 4,240,794) have shown that foreign substances can be substantially firmly anchored in a predetermined location in the body. Because of the inherent ability of fibro-blasts to form scar tissue in and around irregularities of the surface, such anchoring occurs in many locations, including locations within the blood stream.

Therefore, it is a primary object of the present invention to provide an improved method and apparatus for use in reconstructive surgical procedures, with the method employing textured micro particles which may be injected along with an appropriate physiologic vehicle into a predetermined locus within the body.

It is yet a further object of the present invention to provide an improved method and apparatus for use in reconstructive surgical procedures wherein textured micro particles having an outside diameter of between about 20 and 3000 microns may be employed along with an appropriately selected physiologic vehicle for implantation or injection into a predetermined locus.

It is yet a further object of the present invention to provide an improved method and apparatus for use in reconstructive surgical procedures wherein textured micro particles having an outside diameter of between about 20 and

3000 microns may be injected into a predetermined locus of the body for the purpose of filling of defects in reconstructive surgery, with a syringe device having an inwardly tapered outflow tract being desirable for use with particles having a size within the upper range.

Other and further objects of the present invention will become apparent to those skilled in the art upon a study of the following specification, appended claims, and accompanying drawings.

IN THE DRAWINGS

Figure 1 is a perspective view of a textured micro particle useful in accordance with the present invention, and illustrating surface irregularities typically present in the particle;

Figure 2 is a vertical sectional view taken along the line and in the direction of the arrows 2-2 of Figure 1;

Figure 3 is a schematic illustration of a fragmentary portion of human skin organ, and illustrating a hypodermic needle of appropriate size being utilized to introduce materials in accordance with the present invention into the subcutaneous zone beneath a depressed scar;

Figure 4 is a view similar to Figure 3, and illustrating the same location following subcutaneous injection of the textured micro particles in accordance with the present invention;

Figure 5 is a perspective view of a modified form of useful particle wherein the surface irrregularities project outwardly from a body member in pillar form, with the central body portion being in the form of spheroid; and

Figure 6 is a cross-sectional view of the device of Figure 5.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With attention being directed to Figure 1 of the drawings, it will be observed that a micro-implant particle generally designated 10 comprises an inner-core having randomly distributed throughout its surface, various indentations or pores 11-11. These openings or pores are spaced apart by connective pillar members 12. The indentations or pores preferably have a minimum indentation depth or open dimension of about 10 microns, along with a maximum dimension of about 500 microns. The interconnective or pillar zones 12-12 which separate or otherwise define solid material between openings or indentations 11-11 have a dimension or breadth sufficient so that the majority or greater portion of the surface is defined by indentations, openings or pores.

With continued attention being directed to Figures 1 and 2 of the drawings, connective elements 13 are available on the surface of the micro-implant particles and provide for mechanical stability of the individual particle. This arrangement is illustrated in particular in Figure 2.

Prior work by the inventors and others have shown that surface irregularities preferably are in the 20 to 200 micron range in order to achieve adequate contact guidance of the fibroblasts so as to create or develop a scar tissue pattern that is a mirror image of the substrate surface. In this

connection, if the openings, indentations or pores are too shallow in their depth dimension, or in the event their diameter is not sufficiently great, the fibroblasts will tend to bridge across the defect so as to provide a substantially smooth surface. In the preferred embodiment of the present invention, the particles indicated or selected for a specific procedure to assist in correcting a given defect are previously loaded into a hypodermic syringe with a needle having an adequately sized interior bore so that upon injection of the needle into the area of the depression being corrected, the particles together with the appropriate physiologic vehicle enables the spheroids to be injected directly into the area of the depression. Appropriate vehicles, as previously indicated, include physiologic saline or polysaccharide lubricants, each of these enabling the spheroids to be injected as set forth.

With attention being directed to Figure 3 of the drawings, it will be noted that surface tissues as shown at 20 includes a depression area 21, with the depression area extending into the subcutaneous tissue as at 22. For utilization of the concept of the present invention, the needle 23 is shown as it is injected into tissue. Particles 30, of the type illustrated in Figures 1 and 2, along with vehicle 31 are injected into the predetermined site, with the result being filling of the depression area, particularly as illustrated in Figure 4. Upon withdrawal of the needle 23, the injected material is left in situ at the selected site. The supply of particles 30 retained and carried within

vehicle 31 may be conveniently retained in syringe body zone 23A for passage through hollow needle 23. Syringes of this type are, of course, commercially available, and suitable for particles in the low to mid-size range, while larger particles within the size range may require an inwardly tapered outflow tract. For certain applications, it has been found desirable to utilize a syringe-needle combination which tapers continuously, thereby providing an elongated syringe-needle combination with a inwardly tapered out-flow tract.

Upon completion of the inflammatory phase of wound healing, or after approximately one week, formation of scar tissue commences with this becoming complete after about three weeks. Following completion of the deposition and formation of scar tissue, a remodeling phase or operation may be undertaken. In view of the specific irregularities and indentations of the surfaces of the individual particles, contact guidance will normally allow for the resulting scar tissue to firmly anchor and attach the implanted particles 30 wherever deposited. Although various biological substances have been used for similar purposes, such as collagen and fibril, these other previously utilized substances are normally broken down by the body over a period of time and digested autogenously. It is anticipated that the micro particles fabricated of silicone rubber, polytetrafluoroethylene (Teflon), ceramic or other appropriate inert substances will mimic the durometer hardness of the host tissue being filled, with the softer materials, such

as silicone rubber being utilized for normal subcutaneous fat tissue, and with ceramic materials being utilized for bone tissue. Polytetrafluoroethylene (Teflon) is deemed suitable for cartilage, and silicone elastomer with variations in firmness for subcutaneous fat in various regions of the body. In the event the procedure involves an over-correction, the use of lipoplasty techniques of suction lipectomy with a blunt cannula of appropriate diameter will allow for fine tuning, even after several months or years. Removal of an appropriate quantity of filler material may be accomplished in that fashion.

Specific attention is now directed to the modification of particle configuration illustrated in Figures 5 and 6. Specifically, the textured micro particle generally designated 40 comprises a central body portion 41 of generally spheroidal form, together with a number of outwardly projecting pillar members 42-42 thereon. Inter-pillar indentations of generally arcuate form are shown at 43-43. Textured micro particles of the type illustrated in Figures 5 and 6 may also be found useful in connection with the various aspects of the present invention. In actual use, these micro particles will be combined with an appropriate vehicle, of the type previously referred to, such as physiologic saline or polysaccharide lubricant, so as to enable these textured micro particles to be injected into the body. Also, textured micro particles of the type illustrated in Figures 5 and 6 may be formed of the same material as indicated in connection with the embodiment of Figures 1-4, such as for

example, silicone rubber, polytetra-fluoroethylene (Teflon), biocompatible solids such as, for example, hydroxyapatite or other biocompatible solids of the type listed hereinabove.

Radiopaque substances may be utilized, such as, for example, barium compounds to make the particles more visible. In most instances, however, utilization of such radiographic tagging will not be required.

It will be appreciated that the specific examples provided herein are given for purposes of illustration only, and are not to be construed as a limitation upon the scope of the present invention, and that those skilled in the art may depart from the specific examples without actually departing from the spirit and scope of the present invention.

CLAIMS

1. Micro-implantation means for filling bodily defects including soft tissue, firm tissue, and bone tissue and comprising in combination:

(a) inert micro particles dispersed in a physiological vehicle, the micro particles having a textured surface with indentations, cavities, outwardly projecting pillars, and pores generally randomly formed therein;

(b) said textured micro particles having an average particle size generally between about 20 and 3000 microns, and with the dimension of the openings formed by said indentations, cavities and pores within said particles being generally between about 10 and 500 microns.

2. The micro-implantation means as defined in Claim 1 being particularly characterized in that said vehicle is a bodily compatible fluid selected from the group consisting of glucose, starch, silicone fluid, fat, and a lower hylauranodate.

3. The micro-implantation means as defined in Claim 1 being particularly characterized in that said textured micro particles are formed of bodily compatible solids selected from the group consisting of silicone rubber, polytetrafluoroethylene, polyethylene, ceramic, glass and metal.

4. The micro-implantation means as defined in Claim 1 being particularly characterized in that said textured micro particles are of generally uniform configuration.

5. The micro-implantation means as defined in Claim 1 being particularly characterized in that said micro particles comprise a generally spheroidal body portion with outwardly projecting pillars extending therefrom.

6. The micro-implantation means as defined in Claim 1 being particularly characterized in that said micro particles have an average particle size of between (about) 20 and 3000 microns.

7. The method of filling body defects which comprises introducing, in combination, inert textured micro particles dispersed in a physiologic vehicle, and wherein:

(a) the micro particles have a textured surface with indentations, cavities and pores generally randomly formed therein; and

(b) the said textured micro particles have an average particle size generally between about 20 and 3000 microns, and with the dimension of the openings formed by said indentations, cavities and pores being generally between about 10 and 500 microns.

8. The method as set forth in Claim 7 being particularly characterized in that said textured micro particles are selected from the group consisting of silicone rubber, polytetraluoroethylene, polyethylene, hydroxyapatite, and bodily compatible ceramic.

9. The method as defined in Claim 8 being particularly characterized in that said textured micro particles are introduced through a hollow needle having an inwardly tapered out-flow tract.

10. The micro-implantation means as defined in Claim 1 in that said micro particles include a surface modifier selected from the group consisting of polyvinyl-pyrrolidone, collagen, hylauranic acid and a lower alkyl hylauranodate.

11. The micro-implantation means as defined in Claim 10 with the surface modifier being incorporated into the particle substance.